

Novexel Starts Phase II Clinical Trial with NXL103 in Adults with Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

Trial will compare NXL103 with leading oral agent linezolid for the treatment of multi-resistant *Staphylococcus aureus* (MRSA) infections

Paris, France, November 6, 2009 -- Novexel, a speciality pharmaceutical company focused on the discovery and development of novel antibiotics designed to overcome the significant global problem of microbial resistance, announces today that its most advanced oral antibacterial NXL103 (flopristin/linopristin), has started a Phase II clinical trial in adults with acute bacterial skin and skin structure infections (ABSSSI). The trial is designed to assess the safety and efficacy of NXL103 in comparison to oral linezolid (Zyvox, Pfizer NYSE:PFE).

The comparative Phase II trial with NXL103 is a prospective, multicenter, investigator-blinded, two-arm, parallel group study carried out in adults, either in hospital or as outpatients, with ABSSSI. Patients will be randomized to receive either NXL103 (500 mg twice a day) or linezolid (600mg twice a day), with 120 patients receiving NXL103 and 60 receiving linezolid. The treatment period in both study arms will be between 10 and 14 days.

The primary endpoint of the study is the clinical outcome in the clinically evaluable population at the Test of Cure (TOC) visit (7 days post-therapy). Secondary end points of the study include microbiological response at the TOC visit as well as evaluating the tolerability and safety of NXL103.

This comparative Phase II study is expected to recruit a total of 180 patients from approximately 20 sites in the USA and Central America. The study is expected to be completed in 2010 and is a critical part of Novexel's clinical development plan for NXL103 which is focused on its potential to be used in hospitals and out-patients as an oral agent for the treatment of infections caused by Gram-positive organisms, including MRSA. Currently, physicians have a limited choice of anti-MRSA antibacterials when they wish to switch from intravenous (IV) to oral treatment, a key step prior to a patient being able to be discharged from the hospital.

NXL103, as a member of the Streptogramin class of antibiotics, has a unique mode of action, with its two components acting synergistically to inhibit the bacterial ribosome. Its spectrum of activity indicates its potential to be effective in the treatment of ABSSSI, including those caused by resistant pathogens such as MRSA.

In late 2008, Novexel announced positive results from a Phase II clinical trial evaluating NXL103 in the treatment of community acquired pneumonia (CAP).

Iain Buchanan, Novexel's CEO, said, "The start of this Phase II trial with NXL103 is another important step in the growth of the company. There is a clear need for products that can be used to manage the release of patients from hospital by allowing them to be switched from intravenous to oral therapy"

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Notes to Editors

About NXL 103

NXL103 is a novel oral antibiotic made up of two streptogramin antibiotics, linopristin and flopristin, which act synergistically to inhibit the bacterial ribosome. NXL103 is a bactericidal antibiotic and *in vivo* studies have shown that this novel antibiotic is not affected by either beta-lactam or common macrolide resistance mechanisms. Positive results for a Phase II trial with NXL103 in the treatment of community acquired pneumonia (CAP) were reported towards the end of 2008. NXL103 is currently in a Phase II trial for the treatment of ABSSSI.

About ABSSSI

ABSSSI (Acute Bacterial Skin and Skin Structure Infections) are infections that involve deeper tissue or require surgical intervention (e.g. cellulitis, major cutaneous abscesses, and infected wounds) or are associated with a significant underlying disease that complicates response to therapy. A variety of pathogens may be identified in ABSSSI but the two most common Gram-positive pathogens are *Staphylococcus aureus* and *Streptococcus pyogenes*. The significant increase in the incidence of MRSA in community as well as hospital acquired infections has resulted in a need for empirical therapy of ABSSSI that is effective against MRSA.

About Novexel

Novexel is a speciality pharmaceutical company focused on the discovery and development of novel antibiotics designed to overcome the significant global problem of microbial resistance. The ever increasing resistance to marketed antibiotics has led to a clear need for novel drugs that are active against multi-drug resistant bacteria. Novexel's products are targeting the global hospital antibiotic market, which was worth an estimated \$17bn in 2008.¹

In addition to NXL103, Novexel is currently conducting two Phase II studies with NXL104 in combination with the cephalosporin antibiotic ceftazidime (CAZ/104) for serious Gram-negative infections. Patient recruitment in those studies (a) with complicated intra-abdominal infections (cIAIs) and (b) with complicated urinary tract infections (cUTIs) is nearing completion with the results expected in the first half of 2010.

¹ Source: IMS Health, MIDAS, 2006-2008

² "The bacterial challenge: time to react, A call to narrow the gap between multidrug-resistant bacteria in the EU and the development of new antibacterial agents", ECDC/EMA Joint Technical Report, September, 2009

A recent technical report from the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) entitled “The bacterial challenge: time to react,”² voiced the need to narrow the gap between multi-resistant bacteria in the EU and the development of new antibacterial agents. In particular the report highlighted the growing problem of infections caused by multi-resistant Gram negative bacteria including *Pseudomonas aeruginosa*. These are the types of infections that Novexel is targeting with CAZ/104.

Novexel has three further programmes in preclinical development, NXL105, a novel anti-Pseudomonal antibiotic, NXL201, a novel echinocandin antifungal agent, and NXL104 in combination with ceftaroline. This latter product is being developed by Novexel’s partner, Forest Laboratories (NYSE: FRX), solely for North American markets.

Novexel was created in December 2004 as an independent spin-out of the sanofi-aventis (Euronext Paris: SAN, NYSE: SNY) anti-infectives unit. Novexel has a team of 54 employees with significant experience in anti-infective research and development, who are located in Paris, France and Philadelphia, USA.